RESULTS OF INVESTIGATION: The article was a pillow-shaped, padded, cloth-covered device containing an electric motor capable of providing some vibration.

LIBELED: 3–9–60, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for easing nervous tension; relieving aching back; reducing thighs; and aid in reducing.

DISPOSITION: 4–29–60. Default—3 pillows were delivered to the Food and Drug Administration and the remainder were destroyed.

### DRUGS FOR VETERINARY USE

**6199. Kamala Compound Supplement.** (F.D.C. No. 43322. S. No. 45–635 P.)

QUANTITY: 8 25-lb. drums and 5 100-lb. drums at Denver, Colo.

SHIPPED: 4–8–59, from Omaha, Nebr., by Corn States Laboratories, Inc.

LABLE IN PART: "Kamala Compound Supplement Kamala, Tobacco, Iron, Sulphate, Castor Oil and Active Dry Yeast (in a vegetable protein base) for all livestock and poultry. To be mixed with grains, mashes, slop or with salt in self-feeders * * * manufactured by Vitamineral Products Company Peoria * * * Illinois."

ACCOMPANYING LABELING: Pamphlet entitled "Vitamineral Products Company Where a Mixture of Kamala, Tobacco, Iron Sulphate, Castor Oil and Active Dry Yeast (in a vegetable protein base) is specified by veterinarians * * * Directions for feeding."

LIBELED: 7–28–59, Dist. Colo.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for worms in feeder cattle, and that it would benefit gaunt, undernourished off-feed cattle with irregular appetites, intermittent scouring, rough coats, watery eyes, impaired eyesight, over on the fetlocks, stiffness in gaits, swollen joints, lower extremities and briskets.

DISPOSITION: Vitamineral Products Co., Peoria, Ill., appeared as claimant and filed exceptions to the libel as follows: That the warrant of arrest and the return thereof was not in accordance with Admiralty Rule 10 for the United States District Court; that the venue was improper; that the place of seizure was not named; that the libel made no charges against portions of the seized article; that the libel contained a defective jurisdictional allegation; that the libel was not clearly worded; and that the grounds for forfeiture were not stated as required by Admiralty Rule 21.

On 4–6–60, the court entered an order which directed that the Government state more definitely what articles were referred to by use of the words "the aforesaid article" and "the aforesaid articles" appearing in the libel, and which overruled and denied claimant's other exceptions to the libel.

On 6–10–60, the court entered an order of default against the Vitamineral Products Co. for failure to file a claim and answer, and on 6–15–60, the court entered a default decree of condemnation and destruction.

**6200. Ancho-Dine.** (F.D.C. No. 44067. S. No. 97–795 P.)

QUANTITY: 63 1-lb. jars, 9 25-lb. jars, 2 100-lb. jars, at Topeka, Kans.

SHIPPED: Between 12–18–59 and 1–19–60, from St. Joseph, Mo., by the Anchor Serum Co.

LABEL IN PART: "Ancho-Dine for Veterinary Use Only * * * Each Ounce Contains: Active Ingredients: Ethylenediamine Dihydroiodide 4.6% W/W * * * Supplies Readily Available Iodine, Liberated Internally as Hydriodic Acid, in Therapeutic Dosage, Anchor Serum Company, Saint Joseph, Missouri."

ACCOMPANYING LABELING: Booklets entitled "Animal Health References."

LIBELED: 2–17–60, Dist. Kans.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for overcoming mastitis, respiratory conditions, lumpy jaw, and other low-grade infections.

DISPOSITION: 4–7–60. Consent—claimed by Kansas Farmers Union, Topeka, Kans., and relabeled.

## INDEX TO NOTICES OF JUDGMENT D. D. N. J. 6161 TO 6200

### PRODUCTS



[1] (6175) Injunction issued.
[2] (6199) Seizure contested.

# U.S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

# NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6201–6240

## DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or granting a motion for summary judgment, and (2) criminal proceedings terminated upon pleas of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *March 1, 1961.*

## CONTENTS*



*For presence of a habit-forming substance without warning statements, see No. 5707; omission of, or unsatisfactory, ingredients statements, Nos. 6204, 6205, 6227; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6204, 6205; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6204, 6205, 6208, 6237; cosmetic, actionable under the drug provisions of the Act, No. 6213.

*SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6201–6240*

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia) and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative, and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(l), the article was composed in part of penicillin and streptomycin sulfate, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**6201. Andriol and Andriol E.** (F.D.C. No. 44550. S. Nos. 99–842/3 P.)

QUANTITY: 54 1-oz. btls. of *Andriol* and 60 1-oz. btls. of *Andriol E* at Minneapolis, Minn., in possession of Frommes Method, Inc.

SHIPPED: The chemical substances contained in the articles, namely, "Delta 5-Androstene-3 beta, 17 beta Diol" and "Delta 5-Androstene-3 beta, 17 beta Diol Dipropionate," were shipped from Chicago, Ill., prior to the filing of the libel.

LABEL IN PART: (Btl.) "The Frommes Formula Andriol [or "Andriol E"] by Frommes Scalp Specialists, Minneapolis."

RESULTS OF INVESTIGATION: McDonald Laboratories, St. Paul, Minn., manufactured the *Andriol* from the chemical substances shipped in interstate commerce as described above. In addition, isopropyl alcohol was added to the article. Thereafter, the article labeled "*Andriol*" was sold to Frommes Method, Inc., who repacked a portion of the article into 1-oz. bottles. The Frommes Method, Inc., manufactured the *Andriol E* by adding tyrosine, l-lysine, and powdered pine odor to the *Andriol*, and packing such article into 1-oz. bottles.

The above-quoted chemical substances of the articles were new drug substances. The article of *Andriol* was sold and shipped to Frommes Method, Inc.,